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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,520	12/14/2001	Gene Parunak	10255-018-999	3929

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EXAMINER	
SINES, BRIAN J	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/014,520	PARUNAK ET AL.	
	Examiner	Art Unit	
	Brian J. Sines	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-12,14-21,23-28 and 30-37* is/are pending in the application.

4a) Of the above claim(s) *34-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-12,14-21,23-28 and 30-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 3, 5 – 12, 17, 32 & 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Regarding claims 9 – 12, these claims are dependent on canceled claim 4.

2. Claim 2 recites the limitation "the channel" in line 3. There is insufficient antecedent basis for this limitation in the claim.

3. Claim 5 recites the limitation "the downstream region" in line 2. There is insufficient antecedent basis for this limitation in the claim.

4. Claim 17 recites the limitation "polymerase reaction zone" in line 2. There is insufficient antecedent basis for this limitation in the claim.

5. Claim 32 recites the limitation "reagent" in line 2. There is insufficient antecedent basis for this limitation in the claim.

6. Claim 33 recites the limitation "polymerase reaction zone" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 – 3, 5 – 8, 14 – 21, 23 – 28 & 30 – 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pourahmadi et al. (U.S. Pat. Pub. No. US 2002/0055167 A1) (hereinafter "Pourahmadi") in view of Handique et al. (U.S. Pat. No. 6,130,098 A) (hereinafter "Handique").

Regarding claims 1, 15, 18 – 20, 26 – 28 & 30, Pourahmadi teaches an apparatus (cartridge 101) comprising: a sample port (103); a first channel (105); a lysing zone (lysing chamber 119); and second channel (121) leading downstream from the enrichment zone (see paragraphs 0044 & 0048; figure 2). Pourahmadi further teaches that the apparatus can also incorporate one or more filters (e.g., a partitioning structure) for capturing sample components, e.g., cells, spores or microorganisms to be lysed. The filters may also be used for removing particulates, cell debris and protein solids from the sample. The filters may be within any region,

e.g., within the fluid passages or channels leading between regions or within a particular interactive region (see paragraph 0099). Thus, it would have been obvious to a person of ordinary skill in the art to incorporate an enrichment zone or chamber, which comprises a flow-through filter member, positioned upstream of the lysing chamber of the apparatus. In addition, Pourahmadi teach the incorporation of specific electrode configurations comprising a detection zone to allow for the electrochemical detection of chemical constituents in a processed sample (see paragraph 0135). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a detection zone disposed downstream of the enrichment zone to monitor the chemical composition of processed samples.

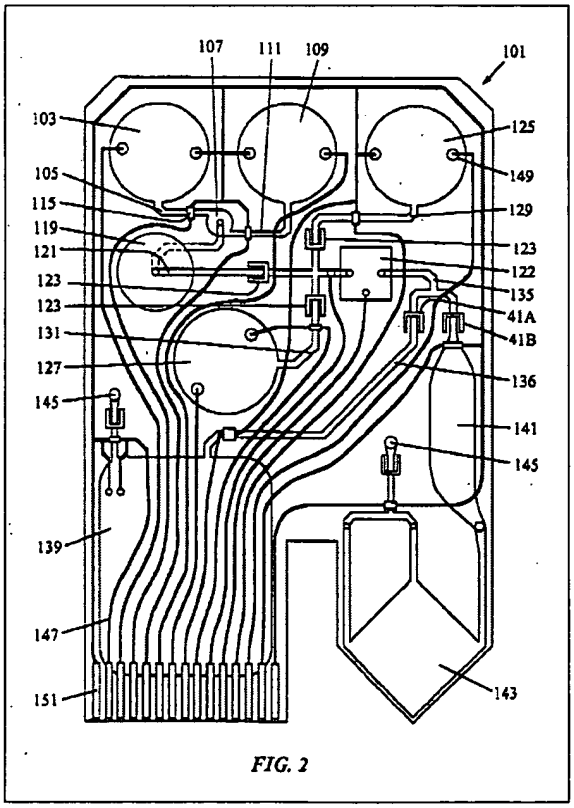

FIG. 2

Pourahmadi does not specifically teach the further incorporation of a gas actuator to facilitate sample fluid flow within the disclosed apparatus. Pourahmadi does teach that a fluid

sample may be introduced into the cartridge by a variety of means, manual or automated (see paragraph 0078). Pourahmadi teaches that for automated sample introduction, additional cartridge design features are employed and, in many cases, impart specimen accession functionality directly into the cartridge (see paragraph 0080). Pourahmadi does further teach that a fluid motive source comprising a pneumatic pressure source can be internally incorporated within the cartridge apparatus for facilitating sample fluid transport (see paragraph 0067).

Handique teaches a thermopneumatic apparatus comprising a gas actuator for facilitating fluid transport in microfluidic devices (see col. 13, line 60 – col. 15, line 40; figures 3A, 3B, 4A & 4B). As shown in figure 4B, the system taught by Handique comprises a thermopneumatic actuating system denoted by 180, a hydrophobic gas vent (170), a positioning element (hydrophobic region 140), and an outlet, which is located to the right of the sample (160) and at the end of the channel containing the sample, from which the sample is transferred for further processing, such as to a lysing chamber for cell lysing, when integrated within an analytical microfluidic system.

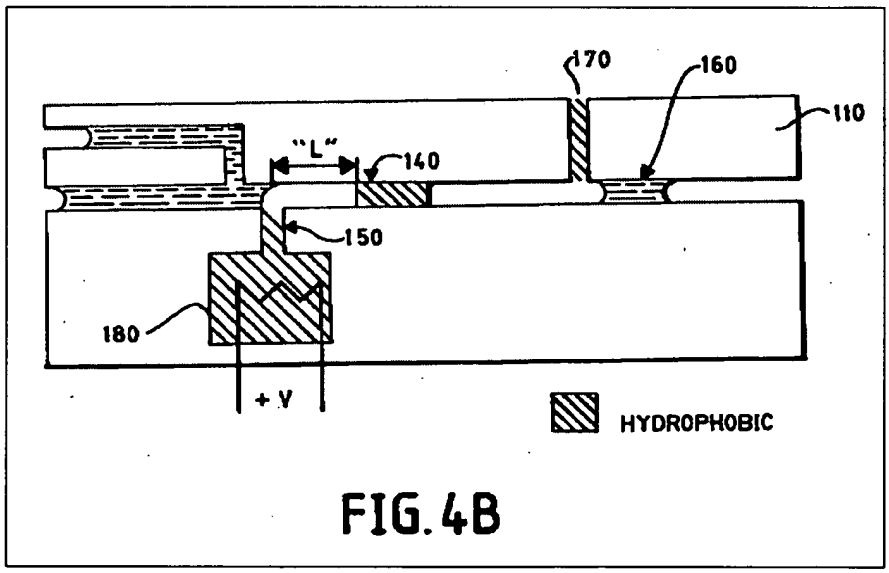

FIG. 4B

Hence, as evidenced by Handique, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success in incorporating such a thermopneumatic fluid transport system with a microfluidic apparatus. The Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate such a thermopneumatic fluid transport system with a microfluidic apparatus for facilitating effective sample fluid transport.

Regarding claim 2, Pourahmadi teaches that the disclosed microfluidic apparatus incorporates a substantially planar substrate configuration (see, e.g., paragraphs 0097 & 0098).

Regarding claims 3 & 21, Pourahmadi teaches that the flow-through or partitioning member comprises a filter, which is inherently anticipated to sieve particles from the sample (see paragraph 0099).

Regarding claims 5 – 7, 23 & 24, Handique suggests the incorporation of valves, which are well known in the art, with the hydrophobic vents (70 & 170) for opening and closing the vents for facilitating sample fluid transport (see col. 14, lines 51 – 57; figures 3A, 3B, 4A & 4B) (see MPEP 2144.03). In addition, Pourahmadi teaches the incorporation of various valves within the disclosed microfluidic apparatus to provide means for controlling fluid transport within the disclosed apparatus (see, e.g., paragraph 0052). Therefore, it would have been obvious to a person of ordinary skill in the art to provide a plurality of valves within the apparatus as claimed in order to facilitate effective sample fluid flow within apparatus.

Regarding claims 8, 17, 25 & 33, Handique teaches that the various features of the microfluidic apparatus are microfabricated and integrated within silicon and glass substrates (see col. 3, line 46 – col. 4, line 10). Pourahmadi also teaches that the disclosed apparatius is microfabricated utilizing glass or silicon structural members as well (see paragraphs 0097 & 0098). Hence, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success in microfabricating an integrated microfluidic apparatus as claimed (see MPEP § 2143.02). Therefore, it would a have been obvious to a person of ordinary skill in the art to microfabricate an integrated microfluidic apparatus as claimed.

Regarding claims 14 & 31, Pourahmadi teaches the incorporation of a cell lysis mechanism utilizing an electrical field to facilitate cell lysis and extraction (see paragraph 0112).

Regarding claims 16 & 32, Pourahmadi teaches the incorporation of a DNA manipulation or polymerase chain reaction zone (reaction chamber 143) for PCR amplification (see paragraph 0054).

Response to Arguments

Applicant's arguments with respect to the pending claims have been considered, but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).